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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,117	02/02/2001	Stephen L. Dewey	BSA 00-34	9414

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,117	DEWEY ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,9,13-20,24,28-31,47-50,54 and 58-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 28, 2003 wherein claims 5, 7, 8, 10-12, 21-23, 25-27, 32-46, 51-53, 55-57, and 62-96 are cancelled; claims 1, 17 and 47 have been amended. Currently, claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 are pending in this application.

Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 as amended now are examined on the merits herein.

The terminal disclaimer filed on November 28, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the copending Application 09/933,157 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's amendment amending claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61, filed November 28, 2003 with respect to the rejection of claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of record stated in the Office Action dated July 29, 2003 has been fully considered and is found persuasive to remove the rejection since the claims have been limited to the particular compound, topiramate. Therefore, the said rejection is withdrawn.

Applicant's amendment amending claims 62-76, filed November 28, 2003 with respect to the rejection of claims 62-76 made under 35 U.S.C. 112 first paragraph for lack of enablement of record stated in the Office Action dated July 29, 2003 has been fully considered and is found persuasive to remove the rejection since the claims have been cancelled. Therefore, the said rejection is withdrawn.

Applicant's amendment amending claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61, filed November 28, 2003 with respect to the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,057,368, of record in the Office Action dated July 29, 2003 has been fully considered and is found persuasive to remove the rejection since the claims have been limited to the particular compound, topiramate. Therefore, the said rejection is withdrawn.

Applicant's amendment amending claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61, filed November 28, 2003 with respect to the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,541,520, of record in the Office Action dated July 29, 2003 has been fully considered and is found persuasive to remove the rejection since the claims have been limited to the particular compound, topiramate. Therefore, the said rejection is withdrawn.

Applicant's amendment amending claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61, filed November 28, 2003 with respect to the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,323,239, of record in the Office Action dated July 29, 2003 has been fully considered and is found persuasive to remove the rejection since the claims have been limited to the particular compound, topiramate. Therefore, the said rejection is withdrawn.

The following is a new rejection necessitated by Applicant's amendment filed on November 28, 2003, wherein the limitations in the claims as amended now have been changed, i.e., the scope has been particularly limited.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 as amended now are rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claims 16-17 and 26-27of U.S. Patent No. 6,395,783.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to methods for changing addiction-related behavior of a mammal suffering from addition to phencyclidine (PCP) and/or ameliorating effects pf PCP addition comprising administering the effective amount of topiramate (see particularly claims 16-17 and 26-27).

The claims of the instant application is drawn to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal suffering from addition to substances broadly herein including PCP, comprising also administering an effective amount of topiramate, the same agent as the patent.

One having ordinary skill in the art would clearly recognize that the method in the patent and the method in the instant application are seen to substantially overlap since the methods in the instant application encompassing the method in the patent.

Moreover, the method steps of the instant application are same as the method steps in the patent.

Thus, the instant claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 as amended now are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 and 26-27of U.S. Patent No. 6,395,783.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (5,189,064 of record) and Phillips (3,639,607, of record) in view of Carmosin et al. (5,332,736, of record).

Blum et al. discloses that GABA and GABA agonists are useful broadly in methods for the treatment of addiction or abuse of drug such as cocaine and alcohol (i.e., reducing seizure activity during alcohol withdrawal) (see 5,189,064 abstract, col.4 lines 30-32 and 64 and 66 in particular) since GABA and GABA agonists increase GABA levels in a mammal (see col.5 lines 2-5). Thus, one of ordinary skill in the art would recognize that seizure activity during alcohol withdrawal would be caused by addiction of alcohol.

Phillips discloses that anticonvulsants are known to be useful broadly in methods of treatment of tobacco addiction, i.e., smoking, and also treating anxiety which accompanies the withdrawal or reduction of the smoking habits in a mammal. See col.1-2.

Blum et al. and Phillips do not expressly disclose the employment of the particular GABA and GABA agonists or anticonvulsants such as topiramate and

its effective amount in methods of diminishing, inhibiting, or eliminating addition-related behavior of a mammal or drug additions herein in a mammal.

Carmosin et al. discloses that topiramate is an anticonvulsant which is known GABA agonists (see col.2 the structure of topiramate at lines 12-20 and lines 24-25), and gabapentin and progabide are known GABAs (col.1 line 60 to col.2 line 23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular GABA and GABA agonists or anticonvulsants such as topiramate and its effective amount in methods of diminishing, inhibiting, or eliminating addition-related behavior of a mammal or drug additions herein in a mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to the particular GABA and GABA agonists or anticonvulsants such as topiramate and its effective amount in methods of diminishing, inhibiting, or eliminating addition-related behavior of a mammal or drug additions herein in a mammal, since anticonvulsants, GABA, or GABA agonists are known to be useful in methods of treating addition-related behavior of a mammal or drug additions herein broadly according to the prior art. Topiramate is all known anticonvulsants, GABA, or GABA agonists.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular anticonvulsants, GABA, or GABA agonists such as topiramate would have same therapeutic usefulness in methods of treating addition-related behavior of a mammal or drug additions herein in a mammal. Additionally, one of

ordinary skill in the art would have been motivated to optimize the effective amounts of these known anticonvulsants, GABA, or GABA agonists used in the methods herein because the optimization of known effective amounts of known active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on November 28, 2003 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant's testing results for topiramate in the Examples 13-14 of the specification at pages 85-86 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Examples 13-14 provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present. Moreover, the clear explanation of pointing out exactly what facts are established therein and relied upon by applicant is not seen in the specification (see page 20). Applicant has

the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974).

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 11, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER
2/22/04